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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,659	02/20/2007	Peter Schwind	BPD-102US	5376
31344	7590	05/18/2009	EXAMINER	
RATNERPRESTIA			NGUYEN, BAO THUY L	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,659	<b>Applicant(s)</b> SCHWIND ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3--23 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/09 &amp; 1/22/09</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2009 has been entered.

### ***Status of the Claims***

2. Claims 1, 3-23 are pending.
3. Claims 10-19 have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-9 and 20—23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Amended claim 1 recites a device where the indicator zones are located between the application zone and the at least one absorption region and are positioned on the membrane substantially parallel to each other and *absent a physical separator between indicator zones*. This device is not supported by the specification as originally filed. Applicant asserts that support for claim 1 can be found at paragraph [0022], however, are careful of this paragraph as well as the entire specification does not reveal adequate support for this limitation. Paragraph [0022] discusses the membrane and its properties as well as flow rate. It does not teach a device where the indicator zones are placed parallel to each other and absent a physical separator between them. Furthermore, figures 1-6 shows a space between the indicator zones thus these drawings actually shows that there is a physical separation between the indicator zones.

In the event that applicant believes support can be found for this limitation, it is respectfully requested that applicant point to the page and line number where such support may be found.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3—4, 6—9 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisberg (US 6,103,536).

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Geisberg teaches a device comprising a single membrane having an application zone, at least one group of indicator zones having reagents appropriate to bind the analytes and at least one absorption region. See column 4, lines 13--38. Geisberg teaches multiple indicator zones for detecting a plurality of analytes and further teaches that for each analyte, a separate series of particular zones and detection zones can be placed in parallel on one comparatively wide strip. See column 8, lines 12-26.

With respect to claim 3, Geisberg teaches that the indicator zones may be arranged in a linear row.

With respect to claim 4, Geisberg teaches antibodies and other ligands. See column 12, lines 42-55.

With respect to claim 6, Geisberg teaches solid support comprising nitrocellulose or fiberglass, etc. See column 8, lines 34-55.

With respect to claims 7 and 9, Geisberg teaches that the solid support can partially or fully enclosed in a moisture-impermeable, inert casing that can be transparent, translucent or opaque. See column 10, lines 54-67.

With respect to claim 8, Geisberg teaches a backing to increase handling strength. See column 10, lines 28-42.

With respect to claim 22, Geisberg teaches a circular confirmation where the sample receiving zone would be placed at the center of the circle and the indicator zones are arranged in concentric rings radiating from the center. See column 8, lines 26-33.

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 20, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg in view of Gordon et al (US 6,100,099).

See the discussion of Geisberg above. This reference differs from the instant claims in failing to teach indicator zones that are arranged diagonal to each other.

Gordon, however, teaches a device comprising a strip of porous material capable of transporting fluids by capillary action, said strip having at least first and second unique capture reagents immobilized thereon in first and second discrete spots spaced apart from an end used to contact transport fluid, said unique first and second capture reagents being specific for different first and second analytes. Where the second spot is spaced from the first spot in both vertical and horizontal dimensions, vertical being the direction of fluid flow. Gordon also teaches that the device may contain three or more spots, each spaced from one another in both vertical and horizontal dimensions to form a substantially linear, diagonal array of spots. See column 4, lines 26-41. Gordon teaches that this arrangement of indicator zones provides the advantage of having a vertical separation to better differential signal from adjacent spots and since having horizontal direction would require a much wider strip in order to achieve the resolution necessary to read the strip, having the diagonal arrangement works best.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the indicator zones taught by Geisberg by arranging them in a diagonal arrangement as taught by Gordon for the advantage of having a vertical separation to better differential signal from adjacent spots and to avoid downstream spots from being shadowed.

**10.** Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg in view of Eisinger et al (US 4,943,522).

See the discussion of Geisberg above. This reference differs from the instant invention in failing to teach antibodies to blood group antigens.

Eisinger teaches device and method for detecting blood group antigens using antibodies. See columns 14-18.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the antibodies taught by Eisinger in the device of Geisberg for detecting blood group antigens because such reagent is well known in the art and Geisberg teaches that their device maybe modify to detect a variety of analytes using appropriate reagents.

### ***Double Patenting***

**11.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**12.** Claims 1 and 3-9 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7, 11-12 and 14-15 of copending Application No. 10/563,681. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Both sets of claims are directed to a device comprising a membrane, an application zone, at least one group of at least two indicator zones, at least one absorption region and the flow directions from the application zone through the indicator zones are substantially parallel and at least two different flow tracks are present.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.



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***Conclusion***

**13.** Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

**14.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,424,220

**15.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
May 12, 2009

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